NOV 0 9 2001

510(k) Summary for BCS™ System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013114

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Rebecca S. Ayash
Preparation date:	September 13, 2001

2. **Device Name/ Classification:**

BCS™ System:	Multipurpose system for *in vitro* Coagulation studies
Classification Number:	Class II (864.5425)

3. **Identification of the Legally Marketed Device:**

Sysmex® CA-6000 System (K001145)

4. **Device Description:**
The current BCS™ System was originally determined to be substantially equivalent as a fully automated photometric coagulation analyzer in 510(k) Premarket Notification K970431. Subsequent to its clearance, the indications for use of the instrument was modified under 510(k) Premarket Notifications, K992959, K000973 and K002080 for the addition of various analytes. The current BCS™ System was cleared to perform coagulometric, chromogenic, and immunochemical tests, such as the routine tests: prothrombin time, partial thromboplastin time, heparin, and fibrinogen, as well as the special tests: single factor determination, antithrombin IIIa, batroxobin, plasminogen, protein C, and D-dimer.

5. **Device Intended Use:**
The Behring Coagulation System performs quantitative assays of specific parameters in human citrated plasma.

6. **Medical device to which equivalence is claimed and comparison information:**
The BCS™ System is substantially equivalent in intended use and results obtained to the Sysmex® CA-6000 System, which was the subject of 510(k) K001145.

7. **Device Performance Characteristics:**

Correlation:
The modified BCS™ System comparison study evaluated plasma samples on the BCS™ System with the Dade Behring LA 1 and LA 2 Reagents versus Dade Behring LA 1 and LA 2 Reagents on the Sysmex® CA-6000 System.

Method Comparison Summary
BCS™ System vs. Sysmex® CA-6000 System

Assay	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
LA1 Screening Reagent (seconds)	202	0.967	y = 0.84 x + 1.05
LA1 Screening Reagent (normalized)		0.967	y = 0.99 x + 0.01
LA2 Confirmation Reagent (seconds)	196	0.956	y = 0.69 x + 1.65
LA2 Confirmation Reagent (normalized)		0.956	y = 0.96 x + 0.04
LA1/LA2 Ratio	194	0.964	y = 1.19 x – 0.00
LA1/LA2 Ratio (normalized)		0.964	y = 1.00 x + 0.00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Dray-Lyons
Manager, Regulatory Affairs
DADE BEHRING, INC.
P.O. Box 6101
Newark, Delaware 19714

NOV 0 9 2001

Re: K013114
Trade Name: BCS™ System
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for in vitro Coagulation Studies
Regulatory Class: II
Product Code: JPA, GGP, GIR
Dated: October 10, 2001
Received: October 16, 2001

Dear Ms. Ayash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 9 2001

Indications Statement

K013114

Device Name: BCS™ System

Indications for Use:

The BCS™ System is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

- Activated Partial Thromboplastin Time (APTT)
- Antithrombin IIIa
- Batroxobin
- D-dimer
- Deficient Plasmas
- Derived Fibrinogen
- Factor V Leiden
- Fibrinogen
- Heparin
- Lupus Anticoagulants
- Prothrombin Time (PT)
- Plasminogen
- Protein C-clotting
- Protein C-chromogenic
- Thrombin Time
- von Willebrand factor

Sylvia Michini for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013114

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

Over-The-Counter-Use ______
(Optional Format 1-2-96)